CONSULTATION SUBMISSION COVER SHEET

This form accompanies a submission on:

TGA Medicine Labelling and Packaging Review Consultation Paper	
Name and designation:	[redacted]
Company/organisation name and address:	iNova Pharmaceuticals Pty Ltd
Contact phone number:	[redacted]

☐ Yes ☒ No	I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)*
☒ Yes ☐ No	I would like my name to be removed from all documents prior to publication and not be included within the list of submissions on the TGA website.

It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, a: (*tick all that apply*)

Business in the therapeutics industry (please tick sector):

☒ Prescription Medicines	☒ OTC Medicines
☒ Complementary Medicines	☐ Medical Devices
☐ Blood/Tissues	☐ Other

☐ Sole trader ☒ Business with 160 employee(s)

☒ Importer ☒ Manufacturer ☒ Supplier ☐ Industry organisation

☐ Government ☐ Researcher ☐ Professional body

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☐ Reg. Affairs Consultant ☐ Laboratory Professional

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inova pharmaceuticals
A Valeant Company

Response to TGA Medicine Labelling and Packaging Review Consultation Paper Version 1.0, May 2012

Thank you for the opportunity to provide comment on the TGA Medicine Labelling and Packaging Review. iNova is a sponsor of prescription, OTC and complementary medicines. Amendments to the Therapeutic Goods Order 69 will have an impact on iNova products and the consumers who use them.

We acknowledge the TGA's view that current medicine labelling and packaging requirements may need to be updated in order to more effectively address some of the concerns of consumers, pharmacists and prescribers. However, a number of the proposals as stated in the consultation document are prescriptive, inflexible and difficult for sponsors to work with. The TGA should provide room for more flexible approaches that could be developed in partnership with sponsors and other stakeholders.

We are concerned that the TGA has not followed the principles and processes described in the COAG Best Practice Regulation Guide (October 2007) and Australian Government Best Practice Regulation Handbook prior to releasing the consultation paper. The COAG Best Practice Regulation Guide outlines a number of principles that should be followed. Among these are: establishing a case for action before addressing a problem; providing a range of feasible policy options that including non-regulatory and co-regulatory options; adopting the option that generates greatest net benefit for the community; providing effective guidance to relevant regulators and regulated parties; consulting effectively; government action being effective and proportional to the issue being addressed.

The TGA has not been transparent in establishing a case for all of the changes proposed in this consultation paper. It has not provided a range of feasible options; there is no documented evidence of any cost-benefit analysis or that the proposed changes will generate the greatest net benefit to the community. The consultation paper does not provide any details on when a Regulatory Impact Statement (RIS) will be prepared, but best practice regulation requires that any regulatory options being considered should be subjected to a regulatory impact assessment process through the preparation of a draft and final RIS[1]. The TGA has not yet produced a draft RIS with the consultation paper.

Australia has scheduling controls and restrictions which mean that most medicines, with the exception of specified lower risk medicines, are available in pharmacies where advice on medicine use, safety and warnings is readily available. This contrasts with some other markets, where the ready availability of large quantities of paracetamol, ibuprofen and other medicines has led to greater safety problems due to misuse and medication errors.

There should be transparency regarding the rationale behind some of the proposed changes and evidence that the changes will make a difference for consumers, prior to imposing the

[1] Australian Government COAG Best Practice Regulation Guide 2007, p.7

burden of excessive change and additional costs on industry. There is concern that some of the proposals in the consultation have been determined arbitrarily and without a solid evidence base. There is no evidence provided that some of the proposed changes will improve safety outcomes for consumers.

The proposals in the consultation document will have a major impact on some products that are already marketed. The TGA should make it clear that the registration status of currently marketed products will not be adversely impacted by changes and that these products should be allowed to continue being marketed.

The amendment of TGO 69 will generate large numbers of variation applications to TGA for labelling changes. Consideration should be given to timelines for approvals and flexibility should be shown, particularly for low volume products and those which are manufactured in infrequent batches.

As part of iNova's comments below, we will provide input on some of these limitations as well as provide proposals for alternative arrangements which may be more workable. Each section is discussed, in the order in which it appears.

Items 1.1, 1.2 – Prominence of active ingredients on labels

We acknowledge that many consumers, pharmacists and the TGA are concerned about the disclosure and print size of active ingredients on medicine labelling, however the proposals put forward by TGA as part of this consultation may be difficult for industry to work with, particularly for OTC medicines.

The proposed requirement for active ingredients on OTC products to be of equal prominence with the brand name, 100% of the font size of the brand name, placed directly under the first letter of the brand name, and in a different style or font, spacing or colour may have the following consequences:

- It will severely restrict and make the use of brand names and designs unworkable in some cases. Branding and design are an important part of a product's heritage and recognition, particularly for OTC medicines where a doctor's involvement is not required and in some cases consumers self-select their medicines.
- For OTC medicines, consumers recognise and often shop for specific brands. Generic purchases are not a significant part of the OTC medicines environment. For example, the market share data for cough products shows that generic or private label products have a market share of only 1% for products supplied in pharmacy[2].
- We question whether it should be necessary for all products, including low risk complementary and other listable products (such as sunscreens and other listable skin products e.g. moisturisers, emollients and personal care products) to have highly prominent active ingredients, given that these are very low risk products with a history of safe use and other characteristics of the product such as SPF number mean more to consumers than active ingredients.

[2] IMS MAT Data June 2012, R05C & R05D

- The TGA's proposal will result in very cluttered, "busy" and confusing looking labels. Cluttered looking labelling may have the unintended consequence of affecting readability and the consumers' ability to readily recognise brands, then locate and understand the information. Generally, medicine labels have only a small amount of space, with much information to include on the main label.
- There is limited space on most labels, and certainly on the side panels and flaps. It will be difficult to give equal prominence to active ingredient names on three faces of a carton, and diminishing the size of the brand name will make it more difficult for pharmacists and assistants to easily distinguish products when viewed from the sides or flaps. Many flaps will not fit all of the required information.
- Products with multiple active ingredients, such as some vitamin products or combination products, will find the active ingredient disclosure requirements difficult to work with. It is inaccurate and confusing for consumers to disclose the three most abundant actives on the main panel, then include all of the other actives and quantities on a side panel.
- Most consumers self-select medicines by looking at the indications or uses of the medicine, rather than the active ingredients. The inclusion of ingredient names that consumers do not understand or cannot pronounce, in large font , at the expense of usage information or indications (which will be severely restricted in size as a consequence), may confuse consumers as many of them will not understand the type, role or function of individual active ingredients.
- Many sponsors perform consumer usability and performance testing on labels. TGA is proposing major changes to legislation without having provided research or evidence that the changes will improve consumer safety and confusion.
- The cluttered appearance of the proposed labels will make it even more difficult to achieve design differentiation for some brands that feature brand extensions and variants as part of the range.

Proposed changes:

INova proposes that some changes should be made to this section:

- Size of active ingredients on OTC product labels could be increased from the current 1.5mm to 2mm or 2.5mm, but equal prominence with the brand name should not be required. This gives sponsors some flexibility around labelling design and the ability to continue with their brand designs.
- For OTC products in particular, there should be some flexibility around the location of active ingredient names, for example these could be located in a contrasting panel or strip, typeface or font on the main label, with flexibility regarding location, thus allowing room for established brand designs and graphics. It should not be necessary to align the active ingredient name directly below the brand name; many brand names are centred on the label not placed from left to right.
- There should be a requirement for some usage information or indications to be present on main panel of OTC product labels, to assist consumer self-selection. Currently, TGO 69 requires a "statement of the purpose or purposes intended for the goods" to be included on the label but not the main label. Consumers self-select for indications rather than actives so this information should have equal prominence.

Item 1.6 – Proposed additional warning for ibuprofen and paracetamol on the front of pack

TGA has stated that additional warning statements should be required for ibuprofen and paracetamol containing products, in not less than 1.5mm font size, stating:

"Contains ibuprofen / paracetamol (as applicable). X mg. Consult your doctor or pharmacist before taking other products for pain or inflammation"

We note the TGA's concerns about paracetamol and ibuprofen and safety issues associated with these products, and acknowledge the need to prevent these occurrences and protect consumers from harm. However, paracetamol and ibuprofen products are already required to carry specific warning statements as required by RASML (Required Advisory Statements for Medicines Labels) and also have scheduling controls and pack size controls. We believe that the Therapeutic Goods Order is not the appropriate mechanism by which warning statements should be regulated, and that RASML remains the appropriate way of determining the need for particular warning statements, assessing the evidence and providing the means for review to take place.

Furthermore, we question the effectiveness of such a warning. Consumers are familiar with reading the back of pack for warning information, yet the proposed front of pack warning statement is a duplication of the currently required back of pack warning. Consumers are not familiar with having warning statements on the front of pack and we question the effectiveness of this approach. It is unlikely that the inclusion of such a warning on the front of pack, with no follow-up direct-to-consumer educational component, will result in safer or more judicious use of paracetamol and ibuprofen products.

The TGA has not provided evidence for the effectiveness of this proposal in markets where similar initiatives have been made. Without transparency and evidence, manufacturers will be required to make major changes that will impact products and consumers, at considerable expense, without any evidence of effectiveness or improvement in patient / consumer safety.

Proposed changes:

iNova proposes that the following changes should be made:

- Paracetamol and ibuprofen labelling and warning statements should remain part of RASML and go through the accepted RASML amendment process, and not be included in the new TGO.
- TGA should provide some transparency and evidence that the proposed action will make a difference to patient or consumer outcomes prior to requiring manufacturers to make a large number of changes to packaging and labelling.

Items 3.1, 3.2, 3.3 – Look-alike / sound-alike names and look-alike packaging

Evidence of risk assessment should not be a routine requirement for labelling applications and should be reserved for situations such as complicated brand extensions that feature many products and look-alike / sound-alike names. This requirement should not be costly or an

additional burden on industry. The TGA should be consultative and open in reaching agreement on any proposed requirements or protocols.
iNova believes that product names and branding are subjects that should not be included in the TGO and are best included within ARGOM, which adequately addresses umbrella branding and discusses elements such as association, differentiation, safety and efficacy. Issues such as branding and naming are best handled during the evaluation process and may require dialogue between the sponsor and the evaluator.

Many sponsors market products that have various actives included under an umbrella brand name e.g. "Nyal". There is no evidence of safety issues or consumer confusion resulting from brand extensions under the "Nyal" umbrella and pharmacovigilance records have not revealed any confusion among consumers, as traditionally these umbrella brands have included different and varying ingredients and consumers are aware of that. Many products are historically marketed under umbrella brands holding various active ingredients – examples are complementary medicines that are umbrella branded under the sponsor's name, as well as various pharmacy private label products.

It is also unnecessarily prescriptive for TGA to specify how many letters difference certain brand names should have in order to be acceptable. These matters should be discussed during the evaluation process and should not be covered under the new Therapeutic Goods Order.

Proposed changes:

iNova proposes the following changes:

- Evidence of risk assessment should not be a routine requirement and should only be needed when there are serious concerns around brand extensions consisting of multiple products and umbrella branding. Development of guidelines should be open and consultative.
- The ARGOM chapter on umbrella branding which discusses association, differentiation, safety and efficacy remains the appropriate way to regulate umbrella branding.
- Naming and branding should continue to be evaluated by the TGA on a case by case basis.
- The "three letters difference" requirement is arbitrary and there is no evidence that it will be effective.

<u>Items 3.4, 3.5, 3.6 – Look alike medicine branding</u>

The TGA has proposed three changes with the aim of reducing consumer confusion and medication errors caused by look-alike medicine branding. iNova believes that the rationale behind the proposed changes is not adequately justified nor has any evidence been provided that there is a problem with medication errors that can only be addressed by the proposed actions.

In some cases, brand names contain both registered and listed products, for example the Hamilton's sunscreen range consists of listed sunscreens as well as a registered sunscreen.

The Nyal brand contains a number of products, some of which are registered and others which are listed on the ARTG. A search of the pharmacovigilance records over the past 3 years (2009-2012) has shown no consumer confusion or medication error due to branding. Consumers rely on the labelling of individual products. Inclusion of listed and registered products under the same umbrella brand should be looked at on a case by case basis, by reference to the relevant section in ARGOM. This issue should not be part of the TGO.

Item 3.5, which states that medicines should not be selectively differentiated or marketed for subsets of symptoms, also should not be included in the TGO and products of this type should be evaluated individually. Not all instances of products marketed for selective indications have an impact on safety, and TGA should not impose a ruling that will adversely impact products that do not pose safety issues. Individual products should be evaluated as per the relevant guidelines and a decision to register or not should be based on the benefit vs. risk of each individual product.

Item 3.6 states that the same brand name should not be applied to products that have different active ingredients or combinations of active ingredients. We believe that this proposal is prescriptive. There are many instances of brand names being used to cover a range of different actives or different combinations of actives with little evidence of safety issues resulting from consumer confusion. This will effectively rule out any growth or extension of brands and will have significant impact on business for many sponsors. Products should be individually evaluated according to guidelines and this type of requirement should not be included in the TGO.

Proposed changes:

- The proposals under items 3.4, 3.5 and 3.6 should not be part of the new TGO and individual products should be evaluated according to ARGOM guidelines and decisions should be made based on the benefit vs. risk of each product at the time of evaluation.

Items 4.1 to 4.6 – Medicines Information Box – standardised back of pack for OTC and Complementary medicines

iNova believes that it is important for labelling to be well designed and use consumer-friendly language. However, the proposed requirement for a standardised Medicines Information Box is prescriptive, and no evidence is supplied that it will improve safety outcomes for consumers. The US FDA "Drug Facts" labelling was legislated in 2000 and implemented in 2002, following consumer research showing that consumers found it difficult to understand some medicine label layout and formats[3]. We believe that the current scenario in Australia is different, given the requirements of the TGO 69 and RASML.

Many companies perform testing on labelling to ensure the usability and performance of their labelling information, and often the labels are developed based on the results of consumer testing. There is no evidence that the standardised format proposed by TGA will improve safety or usage. In some cases it may even detract from performance, as the standardisation

[3] http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143551.htm (Accessed 23rd August 2012)

allows no customisation or individualisation that may be needed to enhance particular aspects of usage, such as diagrams, icons and graphics.

Many products feature consumer focussed designs that include subheadings, shaded boxes, and use of symbols or graphics that have been shown to enhance labelling performance and comprehension. It is a step backwards to impose a "one-size-fits all" totally standardised approach to back of pack labelling for OTC and complementary products.

Most medicine labels are quite small, especially for small OTC packs. Many complementary medicines are in bottles, which do not have more than one face. There is therefore limited space on a label to include all of the information when formatted in the way that TGA suggests and a degree of flexibility with formatting is important when working with small labels. The example back of pack labels in figures 6 and 7 of the consultation are not realistic. Figure 6 is unrepresentative of the size of a typical label, as is figure 7. The example in figure 7 is also unrepresentative in that most medicine product boxes are much smaller than what is featured. In addition, the "Warning and Allergy" sub-heading features a mixture of contraindications, warnings, and allergy information. Consumers find that the sub-headings such as *"Who can use"*, *"Do not use"* , *"Ask your doctor or pharmacist before use"* and *"When to stop"* subheadings are more useful in that the information is easy to locate and provides clear instructions for consumers. The standardised medicine box has no room or flexibility for important information such as tables of age, weight and dosage for some children's medicines.

The proposed changes state that when complete information cannot be shown on the label, this should be included in a pack insert containing the entire Medicines Information Box. This requirement will add to the costs incurred by companies for products, particularly for products in small bottles or containers that are not enclosed in a secondary outer carton or box. The result will be an increase in costs of components.

Standardised back of pack designs for OTC products can sometimes come at the expense of flexibility and are not a neat solution to consumers' reported problems with reading and comprehending labelling information. The TGA needs to consult more widely prior to the introduction of any such requirements, and consideration needs to be given to costs that will be incurred by sponsors.

Proposed changes:

- Some standardisation of back of pack labelling requirements and use of consumer friendly language on labels is important, however the TGA should consult widely and look at alternatives prior to amending the TGO and requiring standardised Medicines Information Boxes in the format described. Sponsors should be free to choose colours and fonts that contrast sufficiently and have flexibility to use graphics, tables and diagrams where needed.
- Consumer focussed or performance based labelling principles should be examined.
- Any amendment to the TGO should provide flexibility with requirements in order to accommodate situations and products that do not fit the standardised model.

Items 5.1, 5.2 and 5.3 – Dispensing label space

While iNova broadly agrees with the requirement to allow space for a dispensing label for prescription medicines, this should be considered as best practice to be followed rather than a mandatory requirement. As such, iNova believes that this should not be mandated as part of a Therapeutic Goods Order. Doing so will mean that it will apply to all medicines, including OTCs and complementary medicines (not only prescription medicines), unless clearly specified.

Items 61, 6.2, 6.3, 6.4, 6.5 – Blister strip labelling

Blister strips are made using the forming, filling then sealing process. For the printing of foils, either of two processes can be used – (i) using lengths of pre-printed foils, or (ii) printing blank foils at the time of manufacture by use of printer plates and printing inks. The batch number and expiry date are then embossed at the time of manufacture, usually at one end of the strip.

Blister strips can usually be designed to accommodate the brand name, active ingredient and amount repeated every two dosage units, as this information is uniform across all batches. Inclusion of information that changes from batch to batch (such as batch number and expiry date) is very difficult to accomplish with current manufacturing set-ups for the following reasons:

- Manufacturers cannot change existing machinery and tooling
- Rolls of foils cannot be pre-printed with batch number and expiry date
- New printing plates cannot be made for every batch of product

The way that blister foils are manufactured and printed is such that batch number and expiry date cannot practically be printed over individual or every two dosage units without major changes to tooling and equipment. These limitations are inherent to the manufacturing process and TGA should not impose requirements that most sponsors and manufacturers will find almost impossible to work with, without major and expensive modifications to equipment and tooling and the need to carry out expensive validations for these changes.

In addition, consumers and healthcare professionals should not be encouraged to remove blister strip medicines from their cartons, as other important safety information (e.g. excipients, preservatives etc.) shown on the outer container will not be available with the product.

Proposed change:

- The existing TGO 69 requirements for blister strips should be retained.

Items 7.1, 7.2, 7.3 – Small containers

The TGA is proposing that small containers should be enclosed in a primary pack and include a pack insert. A list of labelling requirements is also proposed, together with the need to allow some clear space for a dispensing sticker.

iNova believes that the requirement for a small container to be enclosed in a primary pack and include a pack insert should not be mandatory. Sponsors and manufacturers will need to make changes to manufacturing and tooling equipment and this will add to costs, which many overseas manufacturers will be unlikely to make for Australian product that makes up a small proportion of volumes.

The current TGO 69 requires the dosage form and quantity of goods to be included on the label of small containers; however these requirements are missing from item 7.2 of the proposed regulatory changes. We question whether this is an omission.

Proposed change:

- No changes should be made to the current TGO 69 section covering small containers. The changes that are being proposed by the TGA will impose unique requirements for Australian products and will also require changes to packaging equipment in many cases.

Items 8.1, 8.2 – Pack Inserts

iNova believes that pack inserts included with registered medicines should usually be evaluated by TGA and should not include promotional material. Some pack inserts contain educational material for consumers about their symptoms and provide advice on non-drug measures and further information on how to best use the product, and material of this type should be acceptable to evaluators.

In addition, Medicines Australia and TGA have negotiated to allow information on Patient Support Programs and inclusion of enrolment forms as an insert in the product pack. This must not be promotional in nature. TGA have agreed that this information does not require approval from the TGA. No changes should be made to this provision.

Labels and Packaging Advisory Committee

iNova do not believe that an additional Labels and Packaging Advisory Committee is required. The TGA has a number of advisory committees which have sufficient pharmaceutical, medical and pharmaceutical industry and consumer expertise to be able to consider issues relating to labelling and packaging. The Therapeutic Goods Committee (TGC) already considers matters related to packaging and labelling, and the ACNM and ACPM may also provide advice on these matters. Each of the advisory committees includes consumer representation.

We believe that the formation of an additional committee may result in an additional stream of evaluation and delay for sponsors. The TGA has access to expertise that it can use, within the current committee framework.